REMARKS

The Examiner has rejected claims 1-10 for obviousness-type double patenting over claims 1-24 of U.S. Patent No. 6,387,621 (the '621 patent) in view of Herrmann et al. Thus, the Examiner is suggesting that the subject matter of claims 1-10 is an obvious variant of the invention claimed in the '621 patent in view of the disclosure of Herrmann et al. Applicants respectfully traverse the Examiner's rejection of claims 1-10 for obviousness-type double patenting. Claims 1-10 are not obvious over the '621 patent claims in view of Herrmann et al.

Generally, the '621 patent claims are directed to performing a polymerase chain reaction (PCR) in which a baseline fluorescence region is established by confidence band analysis, and ascertaining whether the fluorescence value during a selected amplification cycle is outside the baseline fluorescence region. As conceded by the Examiner, the '621 patent claims do not specify "confirming the results by using a melting temperature analysis."

The claims of the present application specify at least the steps of generating a plot wherein the fluorescence values are recorded for each amplification cycle, performing a confidence band analysis on the plot to generate a positive or negative call, and if the call is positive, confirming the positive call by a melting temperature analysis. Herrmann et al. does not mention or even suggest confirming a positive call generated by confidence band analysis by using a melting temperature analysis. The Examiner indicates that Herrmann et al. teaches "performing a PCR reaction followed by confirming the target using a melting temperature analysis." See page 3, lines 21-22 of the January 30 Office Action. Herrmann et al. simply describes the use of a melting temperature analysis for such analyses as discriminating between alleles (*i.e.*, genotyping) and identifying polymorphisms. Herrmann et al. does not make any suggestion of performing these types of analyses by using real-time PCR in which a confidence band analysis is performed to generate a positive or negative call, and if the call is positive, confirming the positive call by a melting temperature analysis.

In other words, in contrast to Herrmann et al., the presently claimed method is used to perform real-time PCR and to confirm that the signal obtained is a positive call (*i.e*, by 1.) determining a background fluorescence region using a confidence band analysis, and making a positive or negative call based on determination of the background fluorescence region, and 2.) confirming a positive call by using a melting temperature analysis). Herrmann et al. makes no suggestion of using melting temperature analysis in combination with confidence band analysis in such a method. Again, Herrmann et al. simply describes using melting temperature analysis in a method for identifying a target nucleic acid, not for confirming that a result generated by confidence band analysis is a positive call.

The Examiner points to the statements in Herrmann et al. that "The ability to multiplex PCT analysis by color and T_m has many uses in addition to multiplex genotyping. For example, internal amplification controls are often needed for infectious disease and translocation testing to verify that amplifiable DNA or cDNA is present even if the target amplification is negative." However, this statement in no way suggests using melting temperature analysis in the method of claims 1-10 in combination with confidence band analysis. This statement simply suggests that melting temperature analysis can be used to determine whether amplifiable DNA is present. This statement suggests nothing more. Accordingly, the method of claims 1-10 is not obvious over the '621 patent claims in view of Herrmann et al. because Herrmann et al. makes no suggestion of using melting temperature analysis in combination with confidence band analysis as claimed in the method of claims 1-10. Withdrawal of the rejection of claims 1-10 for obviousness-type double patenting is respectfully requested.

The Examiner has also rejected claims 1 and 4-9 under 35 U.S.C. § 103(a) as being unpatentable over Ririe et al. in view of Passing et al. and further in view of Herrmann et al. The Examiner concedes that neither Ririe et al. or Passing et al. teach "confirming the result by a melting temperature analysis." See page 8, lines 7-8 of the January 30 office action.

Again, the presently claimed method is used to perform real-time PCR and to confirm a positive call by 1.) determining a background fluorescence region using a confidence

band analysis, and making a positive or negative call based on determination of the background fluorescence region, and 2.) confirming a positive call by using a melting temperature analysis. Herrmann et al. makes no suggestion of using confidence band analysis in combination with melting temperature analysis to generate a positive call and to confirm the positive call by melting temperature analysis. Herrmann et al. simply describes a method for identifying a target nucleic acid, not for confirming a positive call using both confidence band analysis and melting temperature analysis. According to the Examiner, Ririe et al. and Passing et al. do not teach teach "confirming the result by a melting temperature analysis." Thus, none of the cited references alone or in combination describe or suggest Applicants' claimed method. Withdrawal of the rejection of claims 1 and 4-9 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

The foregoing remarks are believed to fully respond to the Examiner's rejection. The claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,
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